K092460

MAR - 5 2010

510 (k) Summary of Safety and Effectiveness for PS Advanced Engineering StarLite-LM

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the SMDA 1990 and per 21 CFR 807.92

1) General Information

Submitter:

PS Advanced Engineering
200 South Garfield Ave
Suite 318
Alhambra, Calif.
91801

Contact Person:

C D Feak
President
PS Advanced Engineering
200 South Garfield Ave
Suite 318
Alhambra, Calif.
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Summary Preparation Date: 5 August 2009

2) Names

Device Name: StarLite-LM

Classification Name: Laser Instrument, Surgical Powered – General and Plastic Surgery – Class II, Gen 79-GEX

Although this device is not a Laser and is intended for Over The Counter use, the manufacturer believes this is the classification name which is most applicable.

3) Predicate Device

Omnilux New-U (K072459)

4) Device Description

StarLite-LM is a handheld ergonomically designed ABS plastic housed device with a locking Medical Grade Stainless Steel retainer holding in place a Medical Grade polycarbonate lens from which high spectral purity LED light in 2 (two) specific wavelengths is emitted. By design the optical output has a high degree of homogenous light distribution. The output wavelengths are user selected via a simple pushbutton on alternate treatment days and are in the visible Red and the Infrared spectrum. StarLite-LM is powered by a built in Lithium Ion Battery which can be charged as required via a supplied UL listed AC/DC wall mounted unit. Treatment time for both light outputs is controlled by the operator as per Treatment Protocols listed in User Documentation.

5) Indications for Use

The StarLite-LM is a hand held device intended for Over The Counter patient usage to specifically reduce periorbital wrinkles. The target patient population would be identical to the population of the predicate device. StarLite-LM emits LED light energy in the Red and Infrared region.

6) Performance Data

Based on analysis of the performance, safety and effectiveness characteristics for StarLite-LM, PS Advanced Engineering believes that no significant differences in those specific characteristics exists between the StarLite-LM and the previously approved Photo Therapeutics Limited New-U (K072459).

Therefore StarLite-LM raises no new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR – 5 2010

PS Advanced Engineering
% Ms. Wen Yang
President
200 South Garfield Ave, Suite 318
Alhambra, California 91801

Re: K092460
Trade/Device Name: Star-Lite –LM, Model SL8809
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: OHS
Dated: January 29, 2010
Received: February 2, 2010

Dear Ms. Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K092460

Device Name: StarLite–LM

Indications For Use: The StarLite-LM is a hand held device intended for over the counter (OTC) patient usage to specifically treat periorbital wrinkles. The target patient population is identical to that of the predicate device. StarLite–LM emits LED light energy in the red and infrared spectrum.

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092460

Prescription Use _____ AND/OR Over-The-Counter Use ___X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)